

4354-110

Section II (Amendments to the Claims)

Please amend claims 5, 44, 46-48, 59, and 60 as set out in the following listing of the claims of the application.

1. (Original) A pharmaceutical composition comprising a unit dosage form of rifalazil in an amount between 0.1 and 5 mg.
2. (Previously Presented) A pharmaceutical composition comprising a unit dosage form of rifalazil in an amount between 0.1 and 3 mg.
3. (Previously Presented) A pharmaceutical composition comprising a unit dosage form of rifalazil in an amount between 0.1 and 1 mg.
4. (Previously Presented)-A pharmaceutical composition comprising a unit dosage form of rifalazil in an amount between 0.2 and 0.8 mg.
5. (Currently Amended) ~~The~~ A pharmaceutical composition ~~of any of~~ according to claims ~~1 through 3,~~ 1, 2, 3, or 4, wherein said unit dosage is a tablet, pill, capsule, or caplet.
- 6-43. (Cancelled)
44. (Withdrawn - Currently Amended) A method for treating an infection of a bacterium having a multiplying form and a non-multiplying form, said method comprising administering to a patient (i) rifalazil; and (ii) a second antibiotic effective against the multiplying form of said bacterium, wherein said rifalazil is administered in an amount and for a duration effective to treat the non-multiplying form of said bacterium and the second antibiotic is administered in an amount and for a duration effective to treat said multiplying form of said bacterium and wherein said rifalazil is formulated in unit dosages ~~comprising between 0.1 and 5 mg of rifalazil~~ according to Claim 1.
45. (Withdrawn) The method of claim 44, wherein said antibiotic effective against said multiplying form of said bacterium is administered to said patient in an amount and for a duration to reduce the presence of said bacterium in said patient to less than about 10^6 organisms/mL; and rifalazil is then administered to said patient in an amount and for a duration effective to reduce the presence of said bacterium to or below a level indicative that said infection has been treated.

4354-110

46. (Withdrawn - Currently Amended) A method of eradicating non-multiplying bacteria not eradicated in a patient following treatment with a first antibiotic, said method comprising administering rifalazil to said patient in an amount and for a duration effective to eradicate said non-multiplying bacteria in said patient, wherein said rifalazil is formulated in unit dosages ~~comprising between 0.1 and 5 mg of rifalazil~~ according to Claim 1.

47. (Withdrawn - Currently Amended) A method of treating a patient diagnosed as having a chronic disease associated with a bacterial infection caused by bacteria capable of establishing a non-multiplying form phase, said method comprising administering rifalazil to said patient in an amount and for a duration effective to treat said patient, wherein said rifalazil is formulated in unit dosages ~~comprising between 0.1 and 5 mg of rifalazil~~ according to Claim 1.

48. (Withdrawn - Currently Amended) A method of treating the cryptic phase of a bacterial infection, said method comprising administering rifalazil to said patient in an amount and for a duration effective to treat said cryptic phase of said bacterial infection, wherein said rifalazil is formulated in unit dosages ~~comprising between 0.1 and 5 mg of rifalazil~~ according to Claim 1.

49. (Original) A pharmaceutical formulation comprising rifalazil, wherein said formulation is packaged with a label or package insert providing instructions for the use of said formulation, said instructions describing administration of said rifalazil using a loading-dose regimen.

wherein said formulation is provided in a prepackaged therapeutic regimen comprising: a first dosage unit comprising rifalazil; a second dosage unit comprising a smaller dose of rifalazil than said first dosage unit; instructions for the administration of said first dosage unit prior to said second dosage unit; and a pharmaceutical dispensing container prefilled with said dosage units and incorporating said instructions, and

wherein said second dosage unit comprises between 0.1 and 5.0 mg of rifalazil.

50-51. (Cancelled)

52. (Previously Presented) The pharmaceutical composition of claim 3, wherein said unit dosage is a tablet, pill, capsule, or caplet.

4354-110

53. (Previously Presented) A composition comprising

a) rifalazil, in unit dosage form, wherein each dose is in the range of between 0.1 and 5 mg, and

b) instructions for administration on a daily basis for a period of time of at least two consecutive days.

54. (Previously Presented) The composition of Claim 53, wherein the instructions are for daily administration for a period of at least 5 days.

55. (Previously Presented) The composition of Claim 53, wherein the instructions are for daily administration for a period of at least 10 days.

56. (Previously Presented) The composition of Claim 53, wherein the instructions are for daily administration for a period of at least 30 days.

57. (Previously Presented) The composition of Claim 53, wherein the instructions are for daily administration for a period of 4 to 14 days.

58. (Cancelled)

59. (Currently Amended) ~~The A composition of any of~~ according to Claims ~~53-58~~ 53, 54, 55, 56, or 57, wherein the dosage is between 0.1 and 3 mg.

60. (Currently Amended) ~~The A composition of any of~~ according to Claims ~~53-58~~ 53, 54, 55, 56, or 57, wherein the dosage is between 0.1 and 1 mg.

61. (Currently Amended) The pharmaceutical composition of claim ~~47~~ 49, wherein said unit dosage is a tablet, pill, capsule, or caplet.